

Section 5 510(k) Summary

510(k) Owner: Arthrosurface, Inc.
28 Forge Parkway
Franklin, MA 02038
Tel: 508.520.3003
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Contact: Dawn Wilson
VP, Quality & Regulatory

Date of Preparation: July 30, 2012

Trade Name: CheckMate™ Small Bone Fusion System

Common Name: Bone Plates and Screws

Device: Plate, Fixation, Bone
Screw, Fixation, Bone

Regulation Description: Single/multiple component metallic bone fixation
appliances and accessories.
Smooth or threaded metallic bone fixation fastener

Regulation Number: 888.3030
888.3040

Device Class: Class II

Review Panel: Orthopedic

Product Code: HRS
HWC

Intended Use

The CheckMate™ Small Bone Fusion System is intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

Device Description

The CheckMate™ Small Bone Fusion System consists of 2-hole bone plates made available in three length options, and 2.0 mm and 2.7 mm diameter bone screws having lengths varying from 8 mm to 24 mm. The bone plate is pre-assembled with a suture loop intended to provide a traction force required to achieve compression between bone segments. The bone screws have a snap-off feature designed to work with the plates and/or as standalone bone fixation fasteners. The bone plates and screws are manufactured from implant grade stainless steel.

Substantial Equivalency

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

| | |
|--|--------------------|
| • Arthrex, Inc. Distal Extremity Plate System | K111253 |
| • Smith & Nephew VLP Foot Plating, Screw System and Accessories | K090675 |
| • Synthes(USA) Synthes (USA) 2.4/2.7 mm Locking Foot Module Synthes (USA) Modular Mini Fragment LCP System | K071264 K063049 |
| • Wright Medical Technology, Inc. Charlotte™ Compression Plate | K051908 |

Comparative static and dynamic four-point bending test results, along with comparative dimensional and geometric analyses were used to support equivalence to predicate devices.

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 28, 2012

Arthrosurface, Incorporated
c/o Ms. Dawn Wilson
Vice President, Quality and Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K122334

Trade/Device Name: Checkmate Small Bone Fusion System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: November 9, 2012

Received: November 13, 2012

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K122334

Device Name: CheckMate™ Small Bone Fusion System

Indications for Use:

The CheckMate™ Small Bone Fusion System is intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean

(Division Sign-Off)

Division of Orthopedic Devices

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